II 510(k) SUMMARY

DEC 6 2005

K051638

Submitted By:

Unipath Limited
Priory Business Park
Bedford
MK44 3UP
United Kingdom

Contact Person:

Louise Roberts
Unipath Limited
Priory Business Park
Bedford
MK44 3UP
United Kingdom

Date Prepared: 13th June 2005

Proprietary Name: Inverness Medical TestPack + *Plus* Strep A with OBC

Common Name: Rapid immunoassay for the qualitative detection of Group A Streptoccocal antigen from throat swabs.

Classification Name: *Streptococcus* spp. serological reagent test systems to identify *Streptococcus* spp. from cultured isolates derived from clinical specimens.

Predicate Device: QuickVue® Dipstick Strep A Test

Description of the Device: Inverness Medical TestPack + *Plus* Strep A with OBC Strep A is an immunoassay employing sheep and rabbit polyclonal antibodies and gold colloid particles. The test device uses lateral flow technology; following antigen extraction, the test time is approximately 5 minutes (Reference Section "Technological Characteristics").

The Streptococcal Group A specific antigen is extracted from the throat swab using Reagent 1 (2.0 M Sodium Nitrite (& Xylenol Orange) and Reagent 2 (1.0 M Acetic Acid). Following this, Reagent 3 (1.0 M Tris Buffer) is added to neutralise the acid formed by Reagents 1 and 2. The mixture is then dropped into the sample well of the reaction disc from which it migrates through the membrane until it reaches the End of Assay (EOA) Window. As the specimen extract migrates through the membrane, it mobilises the antibody-coated colloid (colloid coated with Rabbit Anti-Strep A antibody). If Group A Streptococcal antigen is present in the specimen it will form a complex with the antibody-colloid. The antibody colloid complex migrates through the membrane and is then captured by the Group A Strep antibody (Sheep polyclonal antibody) in the result window, providing a visual indication of the presence of antigen. The test can be read when the 'End of Assay' (EOA) window has turned pink / red. A pink / red Plus Sign (+) appearing in the result window indicates the presence of the Group A Strep antigen. A Minus Sign (-) indicates no antigen was detected. The device also includes integral Control features as described in "Technological Characteristics".

II. *510(k) SUMMARY* (cont'd)

The Inverness Medical TestPack + *Plus* Strep A with OBC Kit contains:

20 Reaction Discs
20 Dacron-tipped sterile throat swabs
20 Extraction Tubes with Dropper Tips
Reagent 1: 2.0 M Sodium Nitrite (& Xylenol Orange), 10ml
Reagent 2: 1.0 M Acetic Acid, 10ml
Reagent 3: 1.0 M Tris Buffer, 10ml

Intended Use

The Inverness Medical TestPack + *Plus* Strep A with OBC Test is intended for the qualitative detection of Group A Streptococcal (Group A Strep) antigen in throat swab specimens from patients with suspected Group A Strep associated pharyngitis and for confirmation of presumptive Group A Strep colonies isolated on culture plates. The test is intended for Professional and Laboratory Use only.

Technological Characteristics

The Inverness Medical TestPack + *Plus* Strep A with OBC Test which uses lateral flow technology, is similar in technology to other lateral flow immunoassay devices and has the same characteristics and intended use as the predicate device. However, it also includes additional integral control features, as described in this section.
The test employs both sheep and rabbit polyclonal antibodies and a direct label to visualize the immunoreaction indicating the presence of Group A Streptococcal antigen. In the test procedure a throat swab is subjected to a nitrous acid extraction to release Group A Streptococcal antigen. The extracted material is then added, drop-wise, into the Sample Well of the Reaction Disc; the mixture migrates along the membrane and it mobilises the antibody-coated colloid (colloid coated with Rabbit Anti-Strep A antibody). If Group A Streptococcal antigen is present in the specimen it will form a complex with the antibody-colloid; the antibody colloid complex migrates through the membrane and is then captured by the Group A Strep antibody (Sheep polyclonal antibody) in the result window, providing a visual indication of the presence of antigen. The test can be read when the EOA window has turned pink / red. A pink / red Plus Sign (+) appearing in the result window indicates the presence of the Group A Strep antigen. A Minus Sign (-) indicates no antigen was detected.

The test includes the following integral control features:

- Extraction Reagent Control is demonstrated by colour changes during the swab extraction process to indicate that Reagents 1, 2 and 3 are added in the correct order. Reagent 1 is pink, but will change to yellow when Reagent 2 is added. After adding Reagent 3 the solution changes back from yellow to pink. If either of the colour changes does not occur (pink to yellow or yellow to pink), the test is invalid.

- Positive On Board Control (POS CTL √): As the specimen migrates along the test strip the deposited Strep A specific antigen (Analyte Bar) is resolubilised and is captured by the anti-Strep A linked colloid. This complex continues to migrate and is bound by the anti-Strep A antibody to form the POS CTL(√). The POS CTL (√) indicates that both the antibody-colloid complex and capture antibody systems are functional. The POS CTL (√) will appear if the test reagents are working correctly whether there is analyte present in the test specimen or not. The POS CTL (√) must appear for a valid test.

- Negative On Board Control (NEG CTL X): Formation of the NEG CTL (X) in the Result Window indicates that the test specimen may contain a non-specific entity that could cause a false positive result. If the NEG CTL (X) appears in the result window, the test is invalid.

- Minus sign (–): The appearance of the Minus sign (–) indicates that migration of the specimen has occurred across the reaction disc. The absence of the Minus sign (–) may indicate improper addition of extraction reagents or deterioration of the reaction discs. Any colour on the Minus sign (–) should be interpreted as a valid Quality Control result. The Minus sign (–) must appear for the assay to be valid.

- End of Assay Window: The pink or red colour in the End of Assay Window after specimen addition indicates specimen migration has completed across the reaction disc, the test is complete and the result can be read. The pink/red colour must appear in the End of Assay Window for the assay to be valid.

A number of clinical and laboratory performance studies were conducted to determine the substantial equivalence of the test to other commercially available products for the qualitative detection of Group A Streptococcal antigen. These studies are as follows:

- A multi-centre study was conducted to evaluate the clinical performance of the test relative to established culture techniques, to establish substantial equivalence.

- Physicians' Office Studies were conducted to demonstrate that physician office personnel with diverse educational backgrounds, training and work experience can correctly perform and interpret the results of the test.

- Common bacterial organisms and potentially interfering substances, specifically over-the-counter sore throat products, were shown not to interfere with the test's performance.

The clinical performance and laboratory studies conducted demonstrate that the Inverness Medical TestPack + *Plus* Strep A with OBC is substantially equivalent in

its intended use and performance to other diagnostic products for the detection of Group A Streptococcal antigen currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 6 2005

Ms. Louise Roberts
Manager, Regulatory Affairs
Unipath Limited
Priority Business Park
Bedford, MK44 3UP
United Kingdom

Re: k051638
Trade/Device Name: Inverness Medical Testpack + Plus Strep A with OBC
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus Spp. Serological Reagents
Regulatory Class: Class I
Product Code: GTY
Dated: October 11, 2005
Received: October 13, 2005

Dear Ms. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051638

Device Name: Inverness Medical Testpack + Plus Strep A with OBC

Indications For Use:

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051638